



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

August 8, 2014

Division of Dockets Management

HFA-305

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG38, Advanced Notice of Proposed Rulemaking seeking comments on Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations of the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.

The Maryland Department of Health and Mental Hygiene (DHMH) applauds the efforts of the Food and Drug Administration (FDA) to establish regulations regarding deemed tobacco products that further protect public health. In the United States, tobacco use continues to be the leading preventable cause of death, claiming the lives of nearly 500,000 Americans each year, with an additional eight million Americans living with at least one chronic disease related to smoking.¹ In addition to the health effects, the fiscal impact of tobacco use is devastating –nearly \$300 billion is spent annually across the United States on direct medical costs and economic loss due to lost productivity.² If current smoking rates continue, nearly 5.6 million youth under the age of 18 – or 1 in 13 – will die prematurely from smoking.³ This public health crisis must continue to be addressed by the FDA for the health and welfare of our nation.

When the deeming rule takes effect, FDA will for the first time be able to regulate harmful tobacco products, including cigars and e-cigarettes. All of the newly deemed products contain nicotine – a highly addictive drug that can have lasting adverse consequences on the brain of a developing child.⁴ Regulation of these products will be a key step forward in expanding FDA's scope of regulation of tobacco and thus preventing use and addiction, but there is more to be accomplished.

¹U.S. Department of Health and Human Services, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014, available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf> [SGR 2014]

² SGR 2014

³ SGR 2014

⁴ SGR 2014

On behalf of the Maryland Department of Health and Mental Hygiene, I urge the FDA to act more quickly against flavors in cigars and e-cigarettes that mask the harshness of nicotine and are attractive to children and youth. FDA must move decisively before these flavored products hook a new generation and place millions at risk for a lifetime of disability and early death.

Cigars

National data show that cigar use has increased over the past several years. The Surgeon General's Report shows that one out of every five male high school seniors smokes cigars⁵ and the CDC found that cigar use among black high school students increased significantly from 2009-2011.⁶ The CDC also reported that the total consumption of cigarettes decreased by 32.8% between 2000-2011, while non-cigarette combustible tobacco, including cigars and loose tobacco, increased by 123%.⁷ Sweet flavorings mask the harsh taste of tobacco and make them appealing to youth.

In Maryland, we have unfortunately seen first-hand the appeal of flavored tobacco products, particularly cigars, in enticing underage youth into nicotine addiction. Between 2000 and 2013, underage cigarette use declined in Maryland by over 50% – from 23% to 11% – with cigars now surpassing cigarette use as the most popular form of tobacco among this population, at 11.5%.⁸ Further, 71% of youth smoked *flavored* cigars and 48% used more than one type of tobacco product.⁹ According to the Maryland Comptroller's office, between SFY 2001-SFY2011, the total number of cigarette packs sold in Maryland *declined* by approximately 33.6%, while over the same time period, sales of cigar products *increased* by more than 176%.¹⁰

In response to the alarming increase in cigar use among youth in Maryland and across the nation, DHMH developed and launched "*The Cigar Trap*" campaign, with the associated tagline, "*No matter how they sugarcoat it, cigars kill.*" The campaign highlights that these small cigars are available in flavors such as chocolate, vanilla, strawberry, peach, and grape – many of the same popular flavors as ice cream. This health communications effort was aimed to increase awareness and educate Marylanders, especially parents, about the dangers associated with cigar use in order to prevent the often life-long trap of nicotine addiction many young people fall into when they try these appealing products. Focus groups conducted with parents of children between ages 10-20 reinforced that cigars were not seen as being as harmful as cigarettes and the awareness among many adults of their use, and even their existence, was low.¹¹ Once presented visually with small flavored cigars, many participants were visibly shocked and stated, "*My first impression when I looked at the packages is that they don't look like cigar packages. They almost look like candy packages.*" "*Definitely [targeting] kids...because it's fruity or sugary.*" "*I think it's a little sneaky because it doesn't even smell like a cigar. You're not exactly sure what you're buying.*"¹²

⁵U.S. Department of Health and Human Services, Office of the Surgeon General, *Preventing Tobacco Use Among Youth and Young Adults*, March 2012.

⁶Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, August 10, 2012.

⁷Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, August 3, 2012.

⁸DHMH. *Managing Changing Tobacco Use Behaviors*, 2014 (publication pending). Youth Tobacco and Risk Behavior Survey (YTRBS) 2012-13. [MCTUB 2014]

⁹MCTUB 2014

¹⁰FACT SHEET: *Cigar Use among Maryland Youth* http://dhhm.maryland.gov/thecigartrap/PDF/Fact_Sheet_Cigar_Use_among_Maryland_Youth.pdf 2012

¹¹*Youth Cigar Usage Media Campaign Focus Group Report* (unpublished) October 2011

¹²*Youth Cigar Usage Media Campaign Focus Group Report* (unpublished) October 2011

FDA should extend the prohibition against characterizing flavors to all cigars. Although the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) ban specifically applies to cigarettes, FDA may and should extend the ban to cigars to combat the increase in flavored cigar use and the resulting addiction and harm to youth due to the availability and tobacco industry marketing of these products and brands, such as *Swisher Sweets* and *Black and Milds*. Growth of the flavored cigar market is directly linked to the increasing prevalence of flavored cigar use among youth and young adults. Thirty-six percent of middle and high school youth who smoke cigars select flavored brands and young adult cigar smokers report smoking flavored cigars at an even higher rate, with nearly 60% choosing flavored products.¹³

In regard to requested comments on the characteristics or other factors FDA should consider in determining whether a particular tobacco product is a “cigarette” as defined in section 900(3) of the Food, Drug, and Cosmetic Act, FDA should implement the broadest definition of a cigarette for the purpose of determining which products are subject to the characterizing flavor prohibition. The relevant definition includes “any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.” “Little cigars” are the functional equivalent of cigarettes – they are smoked like cigarettes, are about the same size, and are filtered – typically the only difference is the inclusion of tobacco leaf in the wrapper, which makes them appear in color to be the same as cigars. The Surgeon General’s stated that “flavored cigarettes are reemerging as flavored cigars,” due to the fact that flavored cigarettes were banned under the Tobacco Control Act, whereas flavored cigars were not.¹⁴ This appropriate approach to defining products would allow FDA to act far more quickly and ban flavored products under existing provisions in law and regulation.

Electronic Cigarettes

Between 2011-2012, the number of 6th-12th graders who ever used e-cigarettes more than doubled in the U.S.¹⁵ The American Legacy Foundation reports that “awareness of e-cigarettes among young people is nearly ubiquitous, ranging from 89% for those ages 13-17 to 94% for young adults ages 18-21.”¹⁶ The Legacy report further states that e-cigarette advertisers spent \$39 million from June through November 2013 and that the advertising is reaching youth. Additionally, e-cigarettes are impacting our youngest children – the number of calls nationally to poison centers involving e-cigarette liquids containing nicotine rose from one per month in September 2010 to 215 per month in February 2014.¹⁷ The Maryland Poison Center alone received seven calls in 2012 and an additional 11 calls in 2013, with over 70% of the 2013 calls involving children less than six years old.¹⁸ FDA has found that “[m]ore youth who report they would never have used a tobacco product are experimenting with e-cigarettes.”¹⁹ A recent *Journal of the American Medical Association (JAMA)* study also found that middle and high school students who used e-cigarettes were more likely to smoke traditional cigarettes and less likely to quit smoking.²⁰

¹³ King, Brian A., et al., *Flavored Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students*, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, July 29, 2013.

¹⁴ U.S. Department of Health and Human Services, Office of the Surgeon General, *Preventing Tobacco Use Among Youth and Young Adults*, March 2012.

¹⁵ Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, September 6, 2013.

¹⁶ American Legacy Foundation, *Vaporized: E-Cigarettes, Advertising, and Youth*, May 2014. [Legacy 2014]

¹⁷ Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, April 3, 2014.

¹⁸ Maryland Poison Center, February 2014 (unpublished).

¹⁹ Department of Health and Human Services, *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23147 (proposed rule), April 2014.

²⁰ JAMA Pediatrics, *Electronic Cigarettes and Conventional Cigarette Use Among U.S. Adolescents*. 168(7), 2014.

Once the deeming rule is implemented, electronic cigarettes, pipe tobacco, dissolvables and gels, and waterpipe or “hookah” tobacco will all fall under FDA authority, along with cigars. Since electronic cigarettes are “new” tobacco products, entering the market after 2007, they will be illegal to market once the rule takes effect, as they are subject to the requirement that new tobacco products receive FDA pre-market approval. However, with respect to the FDA enforcement discretion to give e-cigarette manufacturers 24 months to apply for FDA authorization to market their products (and then even longer if companies file applications), this compliance period puts youth at continued risk of increased nicotine addiction. FDA should utilize its enforcement authority to take immediate action to protect children and allow e-cigarettes to remain on the market only if their marketing is restricted to adults.

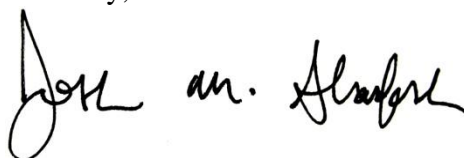
With the proliferation of flavors such as apple pie, bubble gum, and chocolate fudge brownie, e-cigarettes should not be permitted to be flavored or permitted to be marketed in a way that make the products attractive to youth. FDA regulations already have an established set of restrictions to protect children from “conventional” cigarettes – including a ban on flavoring, minimum package size requirements, a ban on self-service displays, and prohibitions on sponsorships and advertising. Once FDA finalizes its deeming rule to bring e-cigarettes under its regulatory umbrella, the agency should use its enforcement discretion to apply all the same restrictions to e-cigarettes immediately to reduce attractiveness and youth access. This approach would stop e-cigarette manufactures from targeting youth far more rapidly than imposing these restrictions through a separate rulemaking process.

Conclusion

With the steps discussed above, FDA can take prompt action on flavors attractive to youth in many cheap cigar products and e-cigarettes. In addition, the Tobacco Control Act authorizes FDA to adopt any tobacco product standard that is “appropriate for the protection of public health,” including prohibiting characterizing flavors. Once the proposed regulation is finalized and tobacco products such as cigars and hookah are deemed subject to FDA’s tobacco product authority, the agency should prohibit characterizing flavors in all remaining tobacco products. Section 907 of the Tobacco Control Act prohibits the use of characterizing flavorings in cigarettes, reflecting a Congressional understanding several years ago that the tobacco industry targets and addicts youth to lethal products through the addition of fruit and candy flavors. A substantive regulation addressing this should not wait until after the deeming regulation is finalized – FDA should begin moving on this issue, as Congress did with flavored cigarettes, to reduce the attractiveness of these products to youth and decrease utilization.

Thank you for your consideration of the clear and present public health threat from flavors in cheap tobacco products – and of the agency’s authority to move quickly and protect children and youth.

Sincerely,

A handwritten signature in black ink, appearing to read "Josh M. Sharfstein". The signature is fluid and cursive, with the first name "Josh" being more prominent.

Joshua M. Sharfstein, M.D.
Secretary